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CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL

No. 34

Introduced by Assembly Member Portantino

**(Coauthors: Assembly Members Beall, Berg, De Leon, Dymally,
Eng, Garcia, Hancock, Horton, Huffman, Jeffries, Lieu, Mullin,
Nakanishi, and Wolk)**

(Coauthor: Senator Romero)

December 4, 2006

An act to add and repeal Article 8 (commencing with Section 1627) of Chapter 4 of Division 2 of the Health and Safety Code, relating to umbilical cord blood banking.

LEGISLATIVE COUNSEL'S DIGEST

AB 34, as amended, Portantino. Umbilical Cord Blood Collection Program.

Existing law, administered by the State Department of Public Health, contains provisions governing the licensure of blood banks, including provisions relating to licensure for purposes of umbilical cord blood

banking *storage services*. Existing law also requires the department to conduct the Umbilical Cord Blood Community Awareness Campaign.

This bill would require the department to establish, by ~~July~~ *January* 1, ~~2009~~ *2010*, the Umbilical Cord Blood Collection Program for the purpose of collecting and storing umbilical cord blood for public use, *as defined*. The bill would require the department to contract with up to 5 *entities, including* blood banks that are licensed or accredited to provide umbilical cord blood banking storage services, to collect, and make available to medical providers and research facilities, umbilical cord blood.

The bill would also establish an implementing committee composed of specified representative members to develop policy recommendations for purposes of implementing the program.

The bill would require the department, in consultation with the implementing committee, to submit to the Legislature and the Governor, 2 reports on the effectiveness of the program by January 1, ~~2012~~ *2013*, and January 1, ~~2017~~ *2018*, respectively, and would require the program to conclude no later than December 31, ~~2018~~ *2019*.

The bill would require that any funds available for purposes of the program be deposited into the Umbilical Cord Blood Collection Program Fund, which this bill would create. The bill would require that the moneys in the fund be available for expenditure, upon appropriation by the Legislature, for that purpose. *The bill would also require that information collected pursuant to the program be confidential, and be used solely for the purposes of the program, as prescribed.*

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) The umbilical cord and placenta are discarded as medical
- 4 waste in about 97 percent of American births. However, the blood
- 5 retrieved from the umbilical cord is rich in stem cells known as
- 6 hematopoietic progenitor cells (HPCs) and can be used today to
- 7 treat about 70 disorders and diseases. These disorders and diseases
- 8 include: (1) blood cancers such as leukemia, myeloma, and
- 9 lymphoma; (2) immunodeficiencies and genetic diseases, including

1 sickle cell anemia, thalassemia, inherited marrow failure disorders;
2 and (3) inherited disorders or errors of metabolisms.

3 (b) Umbilical cord blood has been used successfully in about
4 8,000 transplants since 1988 and has many benefits over bone
5 marrow. The donation procedure, conducted after birth, is painless,
6 quick, and risk free for the mother and newborn baby.

7 (c) The National Marrow Donor Program has the largest registry
8 in the United States that can be searched for a marrow or umbilical
9 cord blood match when stem cell transplants are needed. In order
10 to find the best tissue match for optimal transplant outcome, genetic
11 diversity is needed since a patient's most likely match is someone
12 of the same heritage. According to the National Marrow Donor
13 Program, 35,000 children and adults could benefit from a marrow
14 or an umbilical cord blood transplant each year. The Institute of
15 Medicine of the National Academies estimates patient candidates
16 for HPC transplants to be 11,700 annually.

17 (d) Finding a marrow or blood donor match is challenging for
18 people of all races. Only 30 percent of patients in need of a marrow
19 or an umbilical cord blood transplant find a matched donor in their
20 family. The other 70 percent search registries for an unrelated
21 donor or umbilical cord blood units. Finding a match is particularly
22 difficult for people of color, including people of multiracial
23 ancestry, because they are underrepresented in the national
24 inventory. Many of these patients die while waiting for a transplant.

25 (e) Because most national health and medical organizations do
26 not recommend private umbilical cord blood banking unless there
27 are known health reasons, it is not the intent of the Legislature to
28 collect umbilical cord blood for private use.

29 (f) The Institute of Medicine of the National Academies' report
30 "Cord Blood: Establishing a National Hematopoietic Stem Cell
31 Bank Program (2005)" calls for an increase in the volume and
32 genetic diversity of umbilical cord blood public bank inventory.
33 This report was the basis for establishing the national Stem Cell
34 Therapeutic and Research Act of 2005 which provides for the
35 collection and maintenance of human umbilical cord blood stem
36 cells for the treatment of patients and research. This act dedicated
37 funds for this purpose.

38 (g) California has been a leader in umbilical cord blood
39 transplant research through a number of previous projects including
40 a sibling donor pilot project, through participation in the national

1 study, and its current involvement in the national cord blood
2 program.

3 (h) The national cord blood program has a goal of collecting
4 150,000 genetically diverse units in order to increase the best
5 chances of tissue matches. Due to a low supply of ethnically diverse
6 umbilical cord blood they have specified target collection goals
7 for specific ethnicities, including, but not limited to, Native
8 American, Latino, African-American, and Asian populations, and
9 persons of multiracial ethnicities.

10 (i) California is uniquely situated to add volumes of genetically
11 diverse, high-quality umbilical cord blood units for public banking
12 because of its high birth rate of more than 550,000 births per year
13 and ethnically diverse population. This contribution will not only
14 serve the health needs of California constituents, but can contribute
15 to the national and international umbilical cord blood inventory
16 efforts.

17 (j) An increase in stem cell transplants is also cost effective. It
18 will save the state, insurers, donors, and patients significant moneys
19 now being spent on lifetime medical treatments and relieve ongoing
20 pain and anguish of affected patients and their families.

21 SEC. 2. Article 8 (commencing with Section 1627) is added
22 to Chapter 4 of Division 2 of the Health and Safety Code, to read:

23
24 Article 8. Umbilical Cord Blood Collection Program
25

26 1627. (a) (1) On or before ~~July 1, 2009~~ *January 1, 2010*, the
27 State Department of Public Health shall establish the Umbilical
28 Cord Blood Collection Program for the purpose of collecting and
29 storing umbilical cord blood for public use *for human*
30 *transplantation and human research*. The program shall conclude
31 no later than December 31, ~~2018~~ *2019*.

32 (2) *For purposes of this article, "public use" means both of the*
33 *following:*

34 (A) *The creation of an inventory of genetically diverse umbilical*
35 *cord blood to increase the likelihood of a patient obtaining a*
36 *suitable donor match.*

37 (B) *The use of research protocols approved by the Committee*
38 *for the Protection of Human Subjects or an institutional review*
39 *board, as defined in subdivision (e) of Section 125330, to further*

1 *the understanding of the use of umbilical cord blood as tissue to*
2 *treat human diseases.*

3 (b) In implementing this program, the department shall consider
4 the policy recommendations of the implementing committee
5 established pursuant to Section 1627.5.

6 (c) (1) *In order to implement the program, the department shall*
7 *contract with up to five entities, including entities that are licensed*
8 *or accredited to provide umbilical cord blood collection and data*
9 *processing services, and entities that provide umbilical cord blood*
10 *banking storage services that are licensed or accredited pursuant*
11 *to Section 1604.6, to build an inventory of anonymous umbilical*
12 *cord blood units and make the inventory available to medical*
13 *providers and research facilities for purposes consistent with the*
14 *public use, as defined in paragraph (2) of subdivision (a). A*
15 *medical provider or research facility shall comply with, and shall*
16 *be subject to existing penalties for violations of, all state and*
17 *federal laws with respect to the protection of any medical*
18 *information, as defined in subdivision (g) of Section 56.05 of the*
19 *Civil Code, and any personally identifiable information contained*
20 *in the umbilical cord blood inventory.*

21 (2) *In selecting qualified entities under this subdivision, the*
22 *following shall apply:*

23 (A) *The department may use a competitive process to identify*
24 *qualified entities to administer the program.*

25 (B) *In order to qualify for selection under this section, an entity*
26 *shall have experience in blood collection, labeling, storage,*
27 *transportation, or distribution. The department shall select entities*
28 *with demonstrated ability to retrieve umbilical cord blood from*
29 *ethnically diverse communities.*

30 ~~(e)~~

31 (d) The program shall attempt to meet at least all of the
32 following objectives:

33 (1) Define and identify qualified umbilical cord blood collection
34 entities.

35 (2) Design a competitive process to identify qualified
36 participants licensed or accredited to harvest umbilical cord blood
37 in a manner that complies with state and federal regulations.

38 (3) Establish criteria for determining which units of umbilical
39 cord blood may be used for research versus transplantation, and

1 policy addressing circumstances under which umbilical cord blood
2 may be used for either purpose.

3 (4) Create collection targets for ethnically diverse populations
4 in accordance with identified deficiencies in inventories.

5 (5) Consider a medical contingency response program to prepare
6 for and respond effectively to biological, chemical, or radiological
7 attacks, and other public health emergencies requiring treatment
8 with umbilical cord blood.

9 (6) Develop a public awareness campaign that includes, but is
10 not limited to, activities described in Section 123370.

11 (7) Increase hospital participation in collection and storage
12 efforts, and identify funding sources to offset the financial impact
13 on hospitals.

14 (8) Determine whether the program will require training of
15 health care providers relative to handling, labeling, transporting,
16 and storing umbilical cord blood.

17 (9) Determine policy on obtaining patient consent and timing
18 of consent in relation to existing law and standards of care.

19 (10) Determine whether current law and guidelines applicable
20 to donor confidentiality *and security of donor information* are
21 sufficient and, if they are insufficient, what additional requirements
22 or guidelines are necessary.

23 (11) Determine whether a sibling donor component would help
24 achieve the overall inventory goals of the program.

25 (12) Explore feasibility of operating the Umbilical Cord Blood
26 Collection Program as a self-funding program.

27 (13) Ensure that California's Umbilical Cord Blood Collection
28 Program does not conflict with other state, national, and
29 international efforts to generate an adequate, high-quality
30 inventory.

31 ~~(d) (1) In order to implement the program, the department shall~~
32 ~~contract with up to five entities licensed or accredited to provide~~
33 ~~umbilical cord blood collection, banking, and data processing~~
34 ~~services in accordance with the requirements of Section 1604.6 to~~
35 ~~build an inventory of umbilical cord blood units and make the~~
36 ~~inventory available to medical providers and research facilities.~~

37 ~~(2) In selecting qualified entities under this subdivision, the~~
38 ~~following shall apply:~~

39 ~~(A) The department may use a competitive process to identify~~
40 ~~qualified entities to administer the program.~~

~~(B) In order to qualify for selection under this section, an entity shall have experience in blood collection, labeling, storage, transportation, or distribution. The department shall select entities with demonstrated ability to retrieve umbilical cord blood from ethnically diverse communities.~~

(e) In implementing the program, the department shall make every effort to avoid duplication or conflicts with existing and ongoing programs and to leverage existing resources. The department shall use its existing authority to promote the collection, storage, retrieval, and distribution of umbilical cord blood and advise the Legislature of its needs to accomplish these goals.

(f) (1) All information collected pursuant to the Umbilical Cord Blood Collection Program shall be confidential, and shall be used solely for the purposes of the program. Access to confidential information shall be limited to authorized persons who agree, in writing, to maintain the confidentiality of that information.

(2) Any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section may be denied further access to any confidential information maintained by the department, and shall be subject to a civil penalty not exceeding one thousand dollars (\$1,000). The penalty provided for in this section shall not be construed as to limit or otherwise restrict any remedy, provisional or otherwise, provided by law for the benefit of the department or any other person covered by this section.

(3) Notwithstanding the restrictions of this section, an individual to whom the confidential information pertains shall have access to his or her own personal information.

1627.5. (a) There shall be established, within the State Department of Public Health, an implementing committee to provide guidance and policy suggestions to the department on the implementation of the Umbilical Cord Blood Collection Program created pursuant to Section 1627.

(b) (1) The implementing committee shall be composed of 15 members. The committee shall include representatives with expertise and experience in all aspects of umbilical cord collection and storage. On or before March 1, 2008, the Governor, the Senate

1 Committee on Rules, and the Speaker of the Assembly shall each
2 appoint five members of the implementing committee.

3 (2) The implementing committee shall include all of the
4 following:

5 (A) Two representatives of blood banks licensed or accredited
6 to provide umbilical cord blood services.

7 (B) A representative of a stem cell transplant center that uses
8 umbilical cord blood.

9 (C) Two representatives from hospitals providing labor and
10 delivery services, including one representative from a large hospital
11 system and one representative from an independent hospital. At
12 least one representative shall represent a hospital currently
13 participating in umbilical cord blood collections.

14 (D) Three physicians of different practice types or geographical
15 regions. One physician shall have expertise in umbilical cord blood
16 transplantation, one physician shall have expertise in obstetrics or
17 gynecology, and one shall have expertise in oncology, hematology,
18 or a pediatric specialty that treats children with anemia, immune
19 disorders, or cancers that may be treated with stem cell
20 transplantation.

21 (E) A patient or relative of a patient who has received transplants
22 using umbilical cord blood.

23 (F) A previous donor of umbilical cord blood or a person who
24 has searched or has been involved in searching for an unrelated
25 donor of umbilical cord blood.

26 (G) A person with expertise in typing, matching, and transplant
27 outcome data analysis.

28 (H) A scientist with expertise in stem cell biology.

29 (I) Two representatives of organizations focusing on medical
30 conditions that involve umbilical cord blood treatments or ethnic
31 or racial health disparities.

32 (J) A health plan medical director.

33 (c) Implementing committee members shall serve without
34 compensation, except that members shall be reimbursed for
35 authorized travel costs and expenses.

36 (d) For purposes of implementing the Umbilical Cord Blood
37 Collection Program established pursuant to Section 1627, the
38 implementing committee, by January 1, 2009, shall make initial
39 policy recommendations to the ~~department and the~~ Legislature,
40 *the Assembly and Senate Health Committees, the Assembly and*

1 *Senate Judiciary Committees, the Governor, and the department*
2 on meeting the objectives contained in subdivision ~~(e)~~ (d) of
3 Section 1627.

4 1628. The department, in consultation with the implementing
5 committee established pursuant to Section 1627.5, shall submit
6 two reports to the Legislature, *the Assembly and Senate Health*
7 *Committees, the Assembly and Senate Judiciary Committees*, and
8 the Governor on the effectiveness of the program. The first report
9 shall be submitted no later than January 1, ~~2012~~ 2013, and the
10 second report, no later than January 1, ~~2017~~ 2018.

11 1628.5. (a) The department may accept public and private
12 funds for the purpose of implementing this article.

13 (b) Any funds made available for purposes of this article shall
14 be deposited into the Umbilical Cord Blood Collection Program
15 Fund, which is hereby created in the State Treasury. Moneys in
16 the fund shall be available, upon appropriation by the Legislature,
17 for purposes of this article.

18 (c) The fund shall include any federal, state, and private funds
19 made available for purposes of the program, and, notwithstanding
20 Section 16305.7 of the Government Code, any interest earned on
21 moneys in the fund.

22 1629. This article shall remain in effect only until January 1,
23 ~~2019~~ 2020, and as of that date is repealed, unless a later enacted
24 statute, that is enacted before January 1, ~~2019~~ 2020, deletes or
25 extends that date.